**PATENT**
**ASP5010USNP**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Group Art Unit: 1797

Examiner: Monzer R. Chorbaji

In re application of
Lin et al.

Serial No.: 10/646,296

Filing Date: August 22, 2003

MIST STERILIZATION SYSTEM

## DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Szu-Min Lin, declare the following:

1. I am a named inventor of the above-referenced patent application ("the Subject Application").

2. I am employed by Advanced Sterilization Products, Inc. ("ASP"), a division of Johnson & Johnson, and a subsidiary of Ethicon, Inc. ("Ethicon"), the assignee of the Subject Application as a Research Scientist.

3. I attended the Soochow University in Taiwan and was awarded a Bachelor of Science in Chemistry in 1975. I subsequently attended the University of Texas in Arlington, Texas, United States of America from 1978-1986 and was awarded a Master of Arts in Chemistry, a Master of Science in Computer Science, and a Ph.D. in the area

of Applied Chemistry. In addition, I am a recipient of the Philip B. Hofmann Research Scientist Award and the Johnson Medal Award from Johnson & Johnson.

4. I have been employed at ASP from 1983 to the present. From September 1983 to May 1986, I held the position of Research Chemist; from May 1986 to April 1993, I have held the position of Senior Research Chemist; from April 1993 to June 1996, I have held the position of Senior Research Associate; and from June 1996 to present, I have held the position of Research Fellow. In addition, I coordinate and maintain all patent activity for ASP and currently hold 83 U.S. patents.

5. During my ongoing employment at ASP, I have researched and evaluated various methods and systems for cleaning, disinfecting and sterilizing. I have invented the STERRAD® and STERRAD® NX sterilization systems, which sterilize medical instruments and devices safely and effectively without the limitations or risks associated with peracetic acid, steam, and/or ethylene oxide gas. I am responsible for evaluating various STERRAD® prototypes and defined STERRAD® process parameters. I launched the STERRAD® biological indicator test pack; evaluated and established a biological indicator for STERRAD®, and helped to compile STERRAD® FDA 510(K).

6. It is my understanding that the Examiner of the Subject Application has rejected Claims 1 and 11 of the Subject Application on the grounds that the prior art reference EP 0373201 to Cummings (hereinafter, "Cummings") discloses the claimed invention. Claim 1 recites: "[a] method of disinfecting or sterilizing an article comprising: placing the article into a container; reducing pressure in the container to a first pressure; introducing a mist comprising a sterilant into the container; diffusing the mist through the container into contact with the article; and wherein the first pressure is below

atmospheric pressure and above the vapor pressure of the sterilant whereby to enhance diffusion of the mist throughout the container" (emphasis added). Claim 11 recites: "[a] method of disinfecting or sterilizing an article comprising: placing the article into an enclosure; and reducing pressure in the enclosure to a first pressure to disperse a mist comprising a sterilant throughout the enclosure and into contact with the article." The Examiner asserts that Cummings teaches every element of claims 1 and 11. The Examiner further asserts that "mist" and "vapor" are synonyms of one another (Office Action, pages 2 and 3) and that accordingly, no physical or chemical difference exists between the two terms. The Examiner is factually incorrect.

7. Regarding the physical and chemical distinctions between mist and vapor, mist is made up of small droplets of liquid, in contrast, vapor is gas made up of free molecules. Mist may vaporize into vapor, but mist is not the same as vapor, just as water in liquid phase may vaporize into vapor. In addition, vapor may condense, whereas mist does not condense. Furthermore, mist and vapor differ according to their physical size and weight. For example, mist may be generated with the use of an ultrasound humidifier. The size of water mist generated with ultrasound is typically around 2-10 microns (2-10 $x10^{-6}$ meter), which is visible and significantly larger than water vapor. One 5-micron droplet of water mist weighs about $6.5x10^{-11}$ g and can produce more than one trillion free molecules of water vapor. In contrast, water vapor that vaporizes from liquid water is invisible and can diffuse freely in the air. The bond length in water molecule between oxygen and hydrogen is about $1x10^{-10}$ meter. Each water vapor molecule weighs about $3x10^{-23}$ g. Due to the difference in physical size,

sterile packaging materials are only porous enough to allow the penetration of vapor, but not mist.

8. Mist and vapor compositions of hydrogen peroxide are derived from an aqueous composition of hydrogen peroxide. As indicated in Table 18 of W.C. Schumb, *et al.* "Hydrogen Peroxide," pages 221-227 (Reinhold pub. 1955) (hereinafter, "Schumb"), attached hereto as Exhibit A, mist and vapor compositions are different based on the concentration of hydrogen peroxide in each. Water has a boiling point of 100°C, whereas pure hydrogen peroxide solution has a boiling point of 150°C. Water has a higher vapor pressure than hydrogen peroxide. Therefore, water vaporizes faster and more abundantly than hydrogen peroxide into the vapor phase. For example, 50% liquid composition of hydrogen peroxide can only produce about 7% vapor peroxide at 10°C and 12% at 70°C whereas 50% liquid composition can produce 50% mist composition regardless of the temperature. The concentration of the mist composition of hydrogen peroxide is always the same as the concentration of liquid composition from which it is derived. However based on my experience and supported by the teachings of Schumb, this is not true for vapor compositions. In an enclosed system, the vapor composition of hydrogen peroxide is always less than the concentration of liquid composition from which it is derived until the liquid is completely vaporized. Thus, peroxide mist is different from peroxide vapor based on phase (liquid vs. gas), physical size (mist is significantly larger), physical weight (mist is significantly heavier), penetration ability (mist cannot penetrate sterile packaging material), and composition (mist always has the same composition as the liquid from which it is derived).

9. Accordingly, it is submitted that the "vapor" in Cummings and the "mist" recited in claims 1 and 11 of the Subject Application comprise properties and are physically and chemically different. Any assertion that a hydrogen peroxide "mist" is synonymous with a hydrogen peroxide "vapor" is factually inaccurate for the reasons set forth in paragraphs 7 and 8.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Date 8/22/08

Szu-Min Lin